

**REMARKS/ARGUMENTS**

Claims 36-99 are pending in the present application. By virtue of this response, claims 36, 37, 40, 44, 45, 64, 65, 70, 72, 79, 81, and 88 have been amended. New claims 100-12 have been added. Claims 36 and 64 are amended to recite "one or more heterologous transcriptionally active elements is a transcriptionally active element from a human gene" as suggested by the Examiner. Claim 44 is amended to depend from claim 36. Claims 100-103 are similar to claims 98 and 99, but depend from claims 52 or 58. Support for new claims 100-103 is found in the specification on, *inter alia*, page 13, lines 20-24. New claims 104-106 are similar to claims 68, 77, and 86, but depend from claims 36, 52, or 58. Support for new claims 104-106 is found in the specification on, *inter alia*, page 18, lines 15-18. New claims 107-112 are similar to claims 69, 70, 78, 79, 87, and 88, but depend from claims 36, 52, or 58. Support for new claims 107-112 is found in the specification on, *inter alia*, page 10, lines 26-27; and page 18, lines 12-14. New claims 113-121 are similar to claims 89-97, but depend from claims 64, 71, or 80. Support for new claims 113-121 is found in the specification on, *inter alia*, page 10, lines 28-30; page 19, lines 15-17; and p20, lines 9-11.

For claim consistency, claims 36 and 64 have been amended to recite that the region is "less than about 400 nucleotides in length". *See* claims 52, 58, 71 and 80. One skilled in the art understands that the term "bp" is used interchangeably to refer to single or double stranded forms of a polynucleotide. The term "bp" was also amended to "nucleotides" in claims 37, 65, 70, 72, 79, 81, and 88.

With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application.

**Telephone interview**

Applicant thanks the Examiner for extending the courtesy for a telephone interview on September 10, 2003, with Applicant's representatives Catherine Polizzi and Jie Zhou and for providing helpful suggestions, which are reflected in this response. The substance of the interview,

during which issues raised in the Office Action (including claims rejected in the Office Action) were discussed, as well as a question regarding obviousness-type double patenting, is reflected in this response

**Rejection under 35 U.S.C. 132**

The amendment filed March 3, 2003 is objected to under 35 U.S.C. 132 because new matter is allegedly introduced into the disclosure. The Examiner alleges that the added material, i.e., the change of application 08/445,552 to 08/455,552, is not supported by the original disclosure. The Examiner states that since there is no way to determine which application is the right application to be cited in view of the specification, the change in the application number is not a mere correction of an obvious error. The Examiner further states that the change in the application number introduces new matter into the specification since the specification incorporates by reference all publications and applications cited. The Examiner suggests canceling the new matter.

As discussed during the telephone interview, and in the interest of expediting prosecution, the specification has been amended to recite "U.S. Patent Application 08/445,552". Applicant respectfully requests that the rejection be withdrawn.

**Rejections under 35 USC § 112, second paragraph**

Claims 36-51, 58-70, 80-91, 95-99 are rejected as allegedly indefinite under 35 USC § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claims 36 and 64, the Examiner states that "a human transcriptionally active element" is ambiguous as it could reasonably be interpreted as "an element active in human cells" or as "an element from a human gene", and both interpretations are consistent with the specification. The Examiner further states that based on the support for claim 36 pointed to by Applicant, the Examiner assumes that the intent is the second interpretation. The Examiner suggests that claims 36 and 64 could be amended to recite "a transcriptionally active element from a human gene promoter." With respect to claims 58 and 80, the Examiner states that

the recitation "comprises one or more transcriptionally active elements which are removed from promoter" is confusing since it requires the element to be both present and removed. The Examiner also states that based on the specification on page 24 and the working Examples, it appears that this recitation means that "the element is removed from the context of its original promoter and inserted in the AAV construct". The Examiner asks Applicant to confirm this interpretation.

As a preliminary matter, Applicant respectfully notes that the test for definiteness under 35 U.S.C. §112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). MPEP §2173.02 states "if the claim language used by applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. 112, second paragraph, rather, the examiner should suggest improved language to the applicant." Further, in making a rejection under Section 112, second paragraph, the Examiner must provide an analysis as to why the phrase(s) used in the claim is "vague and indefinite". MPEP §2173.02.

With respect to the Examiner's rejection that claims 36 and 64 are indefinite for reciting "a human transcriptionally active element", Applicant respectfully traverses this rejection. Applicant respectfully submits that it is clear that "a human transcriptionally active element" is a transcriptionally active element from a human gene. The Examiner asked for confirmation that this is correct, and confirmation is hereby given. However, claims 36 and 64, from which claims 37-51, 65-70, 89-91, 98 and 99 depend, have been amended to improve the precision of the claim, and now recite "a human transcriptionally active element from a human gene", using the Examiner's suggested language. This amendment is a non-narrowing, cosmetic amendment. Withdrawal of this rejection is respectfully requested.

With respect to claims 58 and 80, from which claims 59-63, 81-88, and 95-97 depend, Applicant confirms that the recitation "one or more transcriptionally active elements which are removed from a promoter" means that the element is removed from its original promoter.

In view of the above, Applicant respectfully request withdrawal this rejection.

**Allowable subject matter**

Applicant acknowledges with appreciation that the Examiner has allowed claims 52-57, 71-79, 92-94. The Examiner also states that claims 36-51, 58-70, 81-91, and 95-99 are free of the prior art (if interpreted as indicated by the Examiner). The Examiner further states that "the prior art does not teach or suggest constructs with the particulars of the transcriptionally active elements as recited in the claims, within the size limitations required by the claims.

**Double patenting**

The Examiner did not reiterate the rejection of claims under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-35 of U.S. Patent No. 6,346,415. Applicant assumes that the rejection is withdrawn in view of the claim amendment submitted on March 3, 2003.

**CONCLUSION**

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or fees due in connection with this document to **Deposit Account No. 03-1952** referencing docket no. 226272003802

Dated: November 26, 2003

Respectfully submitted,

By   
Catherine M. Polizzi

Registration No.: 40,130  
MORRISON & FOERSTER LLP  
755 Page Mill Road  
Palo Alto, California 94304  
(650) 813-5651  
Attorneys for Applicant